510(k) Summary 807.92(c)

SPONSOR

807.92(a)(1)

Company Name:

Sleeping Well, LLC

Company Address

PO Box 1240

Shelburne, VT 05482

MAR 1 0 2009

Telephone:

802-985-3013

888-978-4389

Fax:

Contact Person:

Daniel A. Webster

Summary Preparation Date: January 20, 2009

DEVICE NAME

807.92(a)(2)

Trade Name:

ZQuiet® Mouthpiece

Common/Usual Name:

Anti-Snoring Device/Mandibular Advancement Device

Classification Name:

Device, Anti-snoring

Regulation Number:

CFR21 872.5570

Product Code:

LRK

Device Class:

Class II

PREDICATE DEVICE

807.92(a)(3)

Legally Marketed Equivalent Device

Company

Product

510(k) #

Tomed Dr. Toussaint GmbH.

Anti-Snoring/Sleep Apnea Device

K061688

DEVICE DESCRIPTION

807.92(a)(4)

The ZQuiet ® Mouthpiece is an Anti-Snoring device consisting of:

- Two trayed plates fitted in front and between the upper and lower teeth and gums and integrated with each other with the same material as the upper and lower plates.
- The device is made of Thermoplastic elastomer
- May be used as supplied

DEVICE INTENDED USE

807.92(a)(5)

The ZQuiet Anti-Snoring device is intended for the treatment of nightime snoring in adults.

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Target Population:

Adult patients

Environment of Use: Home and sleep laboratories

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Substantial Equivalence Discussion

ZQuiet Anti-Snoring Device is similar to the predicate device in intended use, materials and design and does not raise any new issues concerning safety and effectiveness.

NONCLINICAL AND CLINICAL TEST

807.92(b)

SAFETY and EFFECTIVENESS

BIOCOMPATIBILITY

Non-Clinical Performance Data

ZQuiet® Anti-Snoring Device has been evaluated for safety through in vitro tests and animal safety studies.

CONCLUSION

807.92(b)(3)

ZQuiet® Anti-Snoring Device is similar to the predicate device in intended use, materials and design and does not raise any new issues concerning safety and effectiveness.





Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Sleeping Well, LLC C/o Mr. Ned Devine Responsible Third Party Official Underwriters Laboratories Incorporated 333 Pfingsten Road Northbrook, Illinois 60062

MAR 1 0 2009

Re: K090503

Trade/Device Name: ZQuiet® Mouthpiece Regulation Number: 21 CFR 872.5570

Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and

Obstructive Sleep Apnea.

Regulatory Class: II Product Code: LRK Dated: February 20, 2009 Received: February 25, 2009

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal</u> Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.

Acting Director

Division of Anesthesiology, General Hospital, Infection Control and Dental Devices Office of Device Evaluation

& Michau Wax

Center for Devices and Radiological Health

Indications for Use

510(k) Number (if ki	nown): <u>k09.0503</u>
Device Name:	ZQuiet® Mouthpiece
Indications for Use:	
The ZQuiet mandibul snoring in adults.	ar advancement device is intended for the treatment of nighttime
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CFR 801 Subpart I	X (Part 21 AND/OR Over-The-Counter Use (21 CFR 801 Subpart C)
(PLEASE DO NOT	WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)
Concu	rrence of CDRH, Office of Device Evaluation (ODE)
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<u> </u>	Susan Punne
•	n Sign-Off) n of Anesthesiology, General Hospital
	n Control, Dental Devices Page 1 of 1
510(k)	Number: X020503